DEPARTMENT OF HEALTH AND HUMAN SERVICES

912884

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

May 24, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

UTL-01-7769-0

Daniel N. Simon, President
Farm House Food Distributors, Inc.
9000 Woodland Ave.
Cleveland, OH 44104

Dear Mr. Simon:

On April 30/May 1/3, 2001 the Food and Drug Administration (FDA) conducted an inspection of your plant located at the above location. The inspection was conducted to determine compliance with FDA's seafood processing regulations (Title 21 Code of Federal Regulations (CFR), Part 123) and the Good Manufacturing Practices requirements for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves:

(1) Identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and

(2) Having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA Investigator provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483 which presents her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

Your firm's HACCP plan is not adequate to control all of the Critical Control Points, which your operation presents in that the following hazards have not been identified in your plan and/or there are no controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the hazards will occur:

Your firm's HACCP plan does not have appropriate critical limits for the receipt of histamine forming species of fish. You should list in your plan the critical limits for the receiving and holding steps for histamine producing fish.

We encourage you to make the necessary improvements as soon as possible. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards. You should consider using the booklet, *Fish & Fisheries Products Hazards & Controls Guide, Second Edition, Chapter 7* to better understand the potential food safety hazards associated with Scombrotoxin (Histamine) formation as a result of time/temperature abuse of certain species of fish. The booklet is a FDA, CFSAN, Office of Seafood publication that is available at the FDA Internet site: http://vm.cfsan.fda.gov/~dms/haccp-2.html.

The FDA inspection also revealed that your firm's sanitation monitoring records are incomplete in that they do not cover the monitoring of water safety, prevention of cross contamination, labeling and storage of cleaning compounds and protection of food from adulterants. In addition, your firm was not following the procedures stated in your HACCP plan for calibrating the thermometers used in your fish processing operation.

If you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner that the agency should regard as complying with the regulations. In either case, it is essential that you respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system.

If we do not hear from you, or if your response is inadequate, we will assume that our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply relating to these concerns should be should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Mrs. Forney at (513) 679-2700, ext. 163 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program in your plant.

Sincerely,

Deborah Grelle

Deborah Grelle,
Director, Compliance Branch
Cincinnati District